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3 **BEFORE THE ARIZONA MEDICAL BOARD**

4 In the Matter of

5 **AMALIA PINERES, M.D.**

6 Holder of License No. **20943**
For the Practice of Allopathic Medicine
In the State of Arizona.

Board Case No. MD-03-0943A

**FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND ORDER**

(Letter of Reprimand & Probation)

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8 The Arizona Medical Board ("Board") considered this matter at its public meeting
9 on June 10, 2004. Amalia Pineres, M.D., ("Respondent") appeared before the Board
10 with legal counsel Stephen Myers for a formal interview pursuant to the authority vested
11 in the Board by A.R.S. § 32-1451(H). The Board voted to issue the following findings of
12 fact, conclusions of law and order after due consideration of the facts and law
13 applicable to this matter. Respondent subsequently filed a Motion for Rehearing or
14 Review. The State filed a response to Respondent's motion. At its public meeting on
15 February 10, 2005 the Board voted to review and amend the Order portion of the
16 Findings of Fact, Conclusions of Law and Order.

17 **FINDINGS OF FACT**

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19 1. The Board is the duly constituted authority for the regulation and control of
20 the practice of allopathic medicine in the State of Arizona.

21 2. Respondent is the holder of License No. 20943 for the practice of allopathic
22 medicine in the State of Arizona.

23 3. The Board initiated case number MD-03-0943A after receiving notification
24 of a malpractice settlement regarding Respondent's care and treatment of a nine year-
25 old male patient ("DC"). DC's father also filed a complaint with the Board regarding
Respondent's care of his son.

1 4. On July 8, 2002 DC underwent a tonsillectomy and adenoidectomy. At
2 approximately 10:00 a.m. on July 10, 2002 Respondent saw DC in her office. DC
3 complained of significant pain, vomiting, and inability to eat. DC's mother informed
4 Respondent that previously prescribed Tylenol #3 with codeine was not helping DC.
5 Respondent noted that DC was having difficulty swallowing, that his throat showed the
6 usual post-cautery burn and exudates, and that he had mild tender lymphadenopathy.
7 Respondent prescribed two Duragesic 25 microgram patches ("Patch") and gave
8 samples of Augmentin 600 mg .5 ml. with instructions to apply the Patch once every 72
9 hours and to give Augmentin ½ teaspoon twice daily. *The Physician's Desk Reference*
10 ("PDR") that was applicable in 2002 contained a black box warning that the Patch
11 should not be administered to children less than 12 years of age.

12 5. At approximately 5:00 a.m. on July 11, 2002 an emergency room physician
13 called Respondent and advised her that DC had been brought to the emergency room
14 and pronounced dead on arrival. The autopsy report listed fentanyl intoxication as the
15 cause of death and the pathological diagnosis revealed acute fentanyl intoxication.

16 6. After DC's death Respondent was advised that DC had been seen in the
17 emergency room the night of July 8, 2002 and had been given IV fluids, morphine, and
18 Reglan and had been sent home with oral Tylenol #3 with codeine tablets.

19 7. At the beginning of the formal interview Respondent noted that it is
20 extremely difficult and excruciating when a child is under your care and you have to
21 accept that you have somehow failed that child and his family. Respondent stated that
22 she made a mistake and fell below the standard of care when she prescribed the Patch
23 for DC, that she made a judgment call that was wrong. However, Respondent testified
24 that she did not believe that the Patch caused DC's death because, while the autopsy
25 report noted fentanyl intoxication as the cause of death, the fentanyl levels were not

1 toxic or fatal. Respondent also noted that the autopsy report found that DC was very
2 dehydrated. Respondent testified that four months after DC's death a new PDR was
3 issued and it indicates a child two years of age or older can be given the Patch.

4 8. Respondent testified that when DC came to her office he was in serious
5 pain; was not tachycardic; was not febrile; was taking oral pain medication, but was not
6 tolerating it well; was traumatized by the tonsillectomy and adenoidectomy; was very
7 upset; and was nearly hysterical. Respondent testified that she chose not to hospitalize
8 DC and wanted to keep him home with his family. Respondent testified that she used
9 her past experience with the Patch to guide her judgment in this case. Respondent
10 noted that there are not many medications available for pain in pediatric patients.
11 Respondent testified that when she had prescribed the Patch in the past the biggest
12 problem she had was that it did not work; it was not strong enough. As a result,
13 Respondent had to prescribe breakthrough pain medication or increase the Patch to a
14 50, 75 or 100 microgram patch.

15 9. Respondent testified that she had prescribed the Patch off-label in the past
16 at least a few times for her patients. Respondent noted that acute pain is one of the
17 contraindications for using the Patch, but she had seen it used off-label by many
18 physicians. Respondent testified that she knew of physicians who take care of pediatric
19 patients being forced to use OxyContin, which is also a drug that is not recommended
20 for children.

21 10. The Board noted that DC's toxicology report, done postmortem, had the
22 fentanyl level at 16.5 nanograms per mil and that the therapeutic range for analgesic is
23 1 to 3 nanograms per mil. Respondent was then asked whether the concentration of
24 fentanyl on the peripheral blood of DC was significantly greater than that required for
25 analgesia. Respondent noted that it was. Respondent was asked how she could

1 dispute the finding that DC died of fentanyl intoxication when he had a peripheral blood
2 level five times higher than that required for analgesia. Respondent testified that she
3 did not dispute that the Patch could have contributed to DC's death, but she did not
4 believe it was the main cause of his death.

5 11. Respondent was asked what she believed was the main cause of DC's
6 death. Respondent testified that she believed the fentanyl would not have killed DC if
7 he was not septic and also dehydrated. Respondent was asked how the description
8 given by DC's mother of checking on him during the night on several occasions and
9 finding him becoming more drowsy and more sleepy and more and more obtunded as
10 time went on corresponds to what she feels is a septic death as opposed to a
11 respiratory death. Respondent testified that she did not know if she was qualified to
12 describe the difference between a respiratory death and a sepsis death. Respondent
13 was asked what about this case suggests that it was a septic death. Respondent
14 testified that she reached that conclusion partly because DC had positive blood
15 cultures, positive lung cultures, horrid breath, and had not been put on antibiotics.
16 Respondent noted that she did not know if DC developed a fever after she saw him, but
17 if he did, that might be an indication of sepsis. Respondent noted that a spiked fever
18 could also increase the fentanyl levels in the blood. Respondent noted that a respected
19 local pathologist who reviewed DC's case on her behalf opined that the post-mortem
20 fentanyl levels were not toxic and not likely the cause of death.

21 12. Respondent was questioned regarding her decision to send DC home and
22 not admit him to the hospital. Specifically, Respondent was asked if she had taken a
23 history from DC's mother that indicated DC had been seen in the emergency room after
24 the surgery. Respondent testified that she did not know that DC had been to the
25 emergency room subsequent to the surgery and that DC's mother did not tell her he

1 had. Respondent testified that she asked DC's mother what medications he was on
2 and when she answered Tylenol #3 with codeine, Respondent assumed that the
3 surgeon gave DC the medication after the surgery. Respondent also noted that DC
4 was drinking, but not well.

5 13. Respondent was asked if the approximately two and one-half inch note in
6 the record that was dictated on July 10, 2002 was the extent of her examination of DC.
7 Respondent testified that it was and that it was her progress note for that day.
8 Respondent testified that she usually dictates her progress notes immediately after
9 seeing the patient, within two or three patients. Respondent noted that in DC's case
10 the progress note was dictated several hours later because she was called to surgery
11 to assist another physician. Respondent testified that she believed she looked at DC's
12 throat and touched his neck, however DC was afraid of her and was very reluctant to
13 have her examine him.

14 14. Respondent was asked about her past practice of giving the Patch and
15 whether she had given it to a child DC's age or to patients of DC's approximate weight.
16 Respondent stated that she had not. Respondent was asked if she agreed that the
17 normal maximum dosage of fentanyl in an average weight adult (approximately 70
18 kilos), assuming 25 mics per hour in a 70 kilo patient, would be about 0.35 mics per
19 kilo, per hour and that DC essentially got double that dose. Respondent said that in
20 retrospect she sees it that way.

21 15. The standard of care required Respondent to not prescribe a Duragesic
22 patch, a specifically contraindicated opiod medication, to a nine year-old child.

23 14. Respondent fell below the standard of care because she prescribed a
24 Duragesic patch, a specifically contraindicated opiod medication, to a nine year-old
25 child.

1 15. DC died as result of respiratory depression caused by opiate intoxication
2 from the Duragesic patch.

3 **CONCLUSIONS OF LAW**

4 1. The Arizona Medical Board possesses jurisdiction over the subject matter
5 hereof and over Respondent.

6 2. The Board has received substantial evidence supporting the Findings of
7 Fact described above and said findings constitute unprofessional conduct or other
8 grounds for the Board to take disciplinary action.

9 3. The conduct and circumstances described above constitutes unprofessional
10 conduct pursuant to A.R.S. § 32-1401(26)(q) ("[a]ny conduct or practice that is or might
11 be harmful or dangerous to the patient or the public;") and 32-1401(26)(ll) ("[c]onduct
12 that the board determines is gross negligence, repeated negligence or negligence
13 resulting in harm to or the death of a patient.")

14 **ORDER**

15 Based upon the foregoing Findings of Fact and Conclusions of Law,

16 IT IS HEREBY ORDERED that:

17 1. Respondent is issued a Letter of Reprimand for negligently prescribing a
18 fentanyl transdermal patch to a nine year-old child resulting in the child's death.

19 2. Respondent is placed on probation for one year with the following terms
20 and conditions:

21 a. Respondent shall within 12 months of the effective date of this Order obtain
22 10 hours of Board Staff pre-approved Category I Continuing Medical Education ("CME")
23 in pediatric pharmacology and/or pediatric pain management. Respondent shall provide
24 Board Staff with satisfactory proof of attendance. The CME hours shall be in addition to
25 the hours required for biennial renewal of medical license. Respondent's probation will

1 end when she supplies satisfactory proof to Board Staff of her completion of the required
2 CME.

3 b. Respondent shall obey all federal, state and local laws, all rules governing
4 the practice of medicine in Arizona.

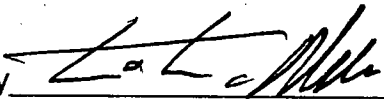
5 c. In the event Respondent should leave Arizona or reside or practice outside
6 the State or for any reason should Respondent stop practicing medicine in Arizona,
7 Respondent shall notify the Executive Director in writing within 10 days of departure or
8 return or the dates of non-practice within Arizona. Non-practice is defined as any period
9 of time exceeding thirty days during which Respondent is not engaged in the practice of
10 medicine. Periods of temporary or permanent residence or practice outside Arizona or of
11 non-practice within Arizona do not apply to the reduction of the probationary period.

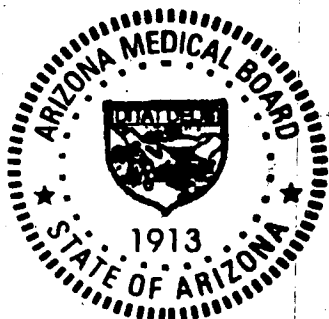
12 **RIGHT TO APPEAL TO SUPERIOR COURT**

13 Respondent is hereby notified that this Order is the final administrative decision of
14 the Board and that Respondent has exhausted her administrative remedies. Respondent
15 is advised that an appeal to superior court in Maricopa County may be taken from this
16 decision pursuant to title 12, chapter 7, article 6.

17 DATED this 10 day of February, 2005.

18
19 THE ARIZONA MEDICAL BOARD

20
21 By 
22 TIMOTHY C. MILLER, J.D.
23 Executive Director
24
25



1 ORIGINAL of the foregoing filed this
2 10th day of ~~FEBRUARY~~, 2005 with:

3 Arizona Medical Board
4 9545 East Doubletree Ranch Road
5 Scottsdale, Arizona 85258

6 Executed copy of the foregoing
7 mailed by U.S. Certified Mail this
8 10th day of ~~FEBRUARY~~, 2005, to:

9 Stephen Myers
10 Myers & Jenkins, P.C.
11 3003 North Central Avenue – Suite 1900
12 Phoenix, Arizona 85012-2910

13 Executed copy of the foregoing
14 mailed by U.S. Mail this
15 10th day of ~~FEBRUARY~~, 2005, to:

16 Amalia Pineres, M.D.
17 Address of Record

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